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PRE-APPEAL BRIEF REQUEST FOR REVIEW

Docket Number (Optional)

006539.00107

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Application Number

10/633,894

Filed

August 4, 2003

First Named Inventor

Scott Powers

Art Unit

1649

Examiner

John Ulm

Applicant requests review of the final rejection in the above-identified application. No amendments are being filed with this request.

This request is being filed with a notice of appeal.

The review is requested for the reason(s) stated on the attached sheet(s).

Note: No more than five (5) pages may be provided.

I am the

☐ applicant/inventor.☐ assignee of record of the entire interest
See 37 CFR 3.71. Statement under 37 CFR 3.73(b) is enclosed.
(Form PTO/SB/96)☒ attorney or agent of record.
Registration number 42,653☐ attorney or agent acting under 37 CFR 1.34.
Registration number if acting under 37 CFR 1.34 _____
SignatureLisa M. Hemmendinger
Typed or printed name202 824-3000
Telephone numberDecember 13, 2005
Date

NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required. Submit multiple forms if more than one signature is required, see below.

☒ *Total of 1 forms are submitted.

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PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

<i>In re</i> Application of:)	
)	Group Art Unit: 1649
Powers <i>et al.</i>)	
)	Examiner: John Ulm
Serial No. 10/633,894)	
)	Atty. Dkt. No. 006539.00107
Filed: August 4, 2003)	
)	Confirmation No. 5609

For: **NOVEL G PROTEIN-COUPLED RECEPTORS**

REASONS SUPPORTING PRE-APPEAL BRIEF REQUEST FOR REVIEW

U.S. Patent and Trademark Office
Customer Service Window
Randolph Building
401 Dulany Street
Alexandria, VA 22314

Sir:

This paper accompanies a Pre-Appeal Brief Request for Review and a Notice of Appeal. We believe no extension fee is due; if this is incorrect, please charge our Deposit Account No. 19-0733.

Claims 42-51 are pending. Claims 43, 46, 50, and 51 are objected to. Claims 42, 44, 45, and 47-49 are rejected as obvious under 35 U.S.C. § 103(a). There are clear errors in this rejection.

Independent claim 42 is directed to a preparation comprising an antibody that specifically binds to the polypeptide of SEQ ID NO:6. Dependent claims 44, 45, and 47-49 recite a polyclonal antibody, a single chain Fv, an F(ab)₂' fragment, an Fab' fragment, and an Fab

fragment, respectively. The Examiner rejected these claims as obvious over Nef.¹ There are clear errors in this rejection.

The Examiner states that the rejection is based on two premises:

1. production of polyclonal antisera was well known when the invention was made; and
2. polyclonal antisera to the protein disclosed in Nef will cross react with the polypeptide of SEQ ID NO:6.

Even assuming these two statements are true, the Examiner has not made a *prima facie* case of obviousness.

First, a *prima facie* case of obviousness must be based on specific factual findings:

[D]eficiencies of the cited references cannot be remedied by the Board's general conclusions about what is "basic knowledge" or "common sense" to one of ordinary skill in the art. . . . This assessment of basic knowledge and common sense was not based on any evidence in the record and, therefore, lacks substantial evidence support. . . . With respect to core factual findings in a determination of patentability, however, the Board cannot simply reach conclusions based on its own understanding or experience -- or on its assessment of what would be basic knowledge or common sense. Rather, the Board must point to some concrete evidence in the record in support of these findings.

In re Zurko, 59 U.S.P.Q.2d 1693, 1697 (Fed. Cir. 2001). *See also In re Kotzab*, 55 U.S.P.Q.2d 1313, 1317 (Fed. Cir. 2000); *In re Lee*, 61 U.S.P.Q.2d 1430, 1434 (Fed. Cir. 2002). There are no specific factual findings in this record to support a *prima facie* case of obviousness. The Examiner merely contends the invention is obvious because production of polyclonal antisera

¹ Nef *et al.*, *Proc. Natl. Acad. Sci. USA* 89, 8948-52, 1992 ("Nef").

was known and antisera which binds to the protein of Nef would bind to the protein of SEQ ID NO:6.

Second, the Examiner cites pages 21 and 22 of Applicants' specification, which describes various antibodies and how to make them generally, as evidence that it would be obvious to produce antibodies to a known protein. Final Office Action at page 4, lines 2-7. This is plain error. Motivation to modify a reference can come from three sources: "the nature of the problem to be solved, the teachings of the prior art, and the knowledge of persons of ordinary skill in the art." *In re Rouffet*, 149 F.3d 1350, 1357, 47 U.S.P.Q.2d 1453, 1457-58 (Fed. Cir. 1998); M.P.E.P. § 2142. The specification cannot be used to provide motivation.

Finally, a reference must be considered as a whole. *Hodosh v. Block Drug Co., Inc.*, 786 F.2d 1136, 1143 n.5, 229 U.S.P.Q. 182, 187 n. 5 (Fed. Cir. 1986); M.P.E.P. § 2141.01. The Examiner has not considered the entirety of the Nef reference. Nef as a whole neither teaches nor suggests any antibodies whatsoever. Nef describes a PCR-based strategy for visualizing distribution of an olfactory receptor in the mouse olfactory system. Nef does not describe antibodies or immunochemistry and does not suggest visualization of the receptor protein itself. Mere disclosure of a receptor protein and a nucleic acid-based means of visualizing its distribution does not suggest making antibodies which bind to the protein. The Examiner's failure to consider Nef as a whole is clear error.

Respectfully submitted,

BANNER & WITCOFF, LTD.

Date: December 13, 2005

Customer No. 22907

By:



Lisa M. Hemmendinger

Registration No. 42,653